

**Application No. 10/647,068  
Docket No. 0101-P02977US1**

**Art Unit: 3732  
Examiner: Philogene, P.**

**REMARKS**

Claims 1-13 are pending in the application, of which claims 1-13 stand rejected.

**PROVISIONAL DOUBLE PATENTING REJECTION**

Claims 1-13 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over various claims of copending Application No. 10/227,161, Application No. 10/161,076 in view of Dunn, Application No. 09/863,234 in view of Dunn, and Application No. 09/026,353 in view of Dunn. Since these are provisional rejections, no action is required of Applicants in response.

**REJECTIONS UNDER 35 U.S.C. 103(a)**

Claims 1-13 stand rejected under 35 U.S.C. 103(a) as “being unpatentable over Coffey (2001/0043943) in view of Dunn et al. (5,717,030).” The Office Action states that with respect to claims 1-13, “Coffey discloses a method for administering, applying, facilitating, treating and healing a reduced pressure treatment to a damaged tissue including a cover, a seal, open cell polymer foam, screen, vacuum port. It is noted that Coffey teaches a substitute material to stabilize a wide variety of anatomical defects but doesn't recite use for hard tissue such as bone. However, in a similar art, Dunn et al evidences the use of a substitute that can be used anywhere in the body including hard tissue such as bone. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Coffey to use the substitute material for bone as taught by Dunn as an obvious equivalent alternative treatment as suggested by the prior art.”

Applicants respectfully disagree that the proposed modification of Coffey in view of Dunn is obvious, for at least the reasons that 1) there is no motivation found within the references themselves or knowledge generally available to one skilled in the art to make the proposed combination, 2) there is no reasonable expectation of success, and 3) the modification would render Dunn inoperable, or at least less effective, for its intended purpose.

Applicants' claimed invention is directed to an apparatus and method for treatment of damaged bone tissue or a bone defect through the application of reduced pressure. As evidenced

by Coffey, as well as the seminal patents in this area (US 5,645,081 and 5,636,643, each of which were acknowledged by and incorporated by reference in Coffey and each of which are owned by the assignee of the present application), devices and treatment methods in the field of reduced pressure therapy have been directed to treatment of soft tissues, with the expectation and understanding that soft tissues might be amenable to treatment by reduced pressure therapy, because soft tissue can contract and deform in response to the application of reduced pressure. That is, a person skilled in the art would understand that the reasons for successful treatment in Coffey were postulated to be due to mechanisms that could be expected to affect soft tissue but would not be expected to affect hard tissue to a significant degree.

For example, the '081 patent to Argenta and Morykwas teaches that "wound closure requires that epithelial and subcutaneous tissue migrate from the wound border toward the wound. The use of negative pressure provides tension on this border tissue that causes accelerated tissue migration [which] .... also causes within the wound increased formation of granulation tissue, a matrix of collagen, fibronectin, and hyaluronic acid carrying macrophages, fibroblasts, and neovasculature that aids in healing." (Emphasis Added. Column 2, lines 49-58.). Thus, the expectation and knowledge of one skilled in the art for successful use of reduced pressure were limited to treating those tissues which are able to be placed in tension in response to application of reduced pressure, namely soft tissues. Hard tissues, such as bone, are not placed in tension in response to the application of reduced pressure, like soft tissues are. For example, while the opposite ends of a soft tissue wound can be pulled together by simply using one's fingers or reduced pressure therapy, the opposite ends of a bone cavity or bone hole cannot. Consequently, one of the healing mechanisms believed to be useful for the vacuum treatment of soft tissue wounds simply does not exist for bone cavities and defects. Thus, there would have been no expectation of one skilled in the art that the application of reduced pressure to bone tissue would provide the type of effect disclosed in Coffey. Indeed, Coffey apparently did not appreciate this, because, in keeping with the prevailing thinking of the time, Coffey disclosed only the treatment of soft tissues. Coffey does not disclose treatment of hard tissue and does not ever suggest such a use, because it is not obvious that a device that promotes healing in soft tissue will also promote healing in a rigid material such as bone.

In order for an examiner to establish a *prima facie* case of obviousness under 35 U.S.C. 103:

- (i) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings;
- (ii) there must be a reasonable expectation of success; and
- (iii) the prior art reference (or references when combined) must teach or suggest all the claim limitations. (MPEP 706.02 (j)).

Section 706.02 (j) of the MPEP also provides that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not be based on applicant's disclosure, citing In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In the instant case, there is no suggestion or motivation to make the proposed combination, and there is no reasonable expectation of success in combining the references, for at least the reasons that all the references relied upon in the rejection fail to recognize that bone tissue can be beneficially affected through the application of reduced pressure. In fact, as explained above, a person skilled in the art at the time the invention was made understood that negative pressure was effective in treating soft tissue because the soft tissue could be placed under tension to induce tissue migration. Since the person of ordinary skill in the art understood that this tension and tissue migration were a basic component of a successful treatment with reduced pressure, the person of ordinary skill in the art would never be motivated to make the proposed prior art combination, because hard tissue, such as bone, is not expected to undergo tension or tissue migration in response to reduced pressure. Indeed, based on the teachings of the asserted prior art, a person of ordinary skill in the art would in fact have no reasonable expectation of success. Traditionally, one skilled in the art understands that mechanical systems such as pins and fixators and distractors are required to place bone tissue under tension.

Turning then to the references, Coffey relates merely to a vacuum bandage for use in treating surface wounds (i.e., soft tissue injuries). As such, Coffey fails to recognize, disclose, or suggest that the vacuum environment can have any effect whatsoever on hard tissue. Indeed,

Coffey neither mentions bone tissue nor suggests any hard tissue treatment using reduced pressure. Dunn on the other hand, makes no mention whatsoever of reduced pressure. Dunn merely relates to “a surgically implantable device coated with an adjunctive polymer system... [that] can contain a drug or medicament which is released over time from the solid matrix [of the adjunctive polymer system].” (Abstract.) Thus, while Dunn does mention bone tissue, Dunn does not disclose or suggest reduced pressure. As such, Dunn fails to supply both the motivation to make the proposed combination of a reduced pressure system with hard tissue, (the teaching missing from Coffey), as well as the reasonable expectation that such a combination would be successful that is also missing from Coffey. It is only through hindsight that Examiner has combined Coffey and Dunn. For the above reasons, Applicants respectfully submit that the proposed prior art combination of Coffey with Dunn is insufficient, at the very least because there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings, and there is no reasonable expectation of success. However, yet additional reasons exist for concluding the proposed combination of Coffey with Dunn is inappropriate.

It has long been held that it can never be obvious to combine references where the proposed combination would render the device of the prior art unsuitable for its intended purpose. A modification that renders a reference less suited for its intended purpose is never obvious. Gordon, 1127. In the instant case, Applicants respectfully submit that combining Coffey with Dunn would render the device of Dunn less suited for its intended purpose.

A principle purpose of the Dunn system is to provide a surgically implantable device coated with an adjunctive polymer system that can contain a drug or medicament which is released over time from the solid matrix. (Abstract.) Specifically, Dunn teaches that “[w]hen used near or in conjunction with bone tissue, the adjunctive polymer system preferably contains a biologically active agent to prevent infection and aid in healing.” (Column 15, lines 27-29.) Dunn further explains that the “bioactive material will be released from the matrix into the adjacent tissues...” (Column 12, lines 31-32, emphasis added.) Thus, Dunn discloses generic surgically implantable devices that are coated with an adjunctive polymer system that can serve as a drug delivery vehicle. In order for the adjunctive polymer system of Dunn to be effective,

**Application No. 10/647,068**  
**Docket No. 0101-P02977US1**

**Art Unit: 3732**  
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however, the drugs being released must reach the tissues to be treated. In contrast, however, modifying the device of Dunn to provide the vacuum bandage of Coffey over it, as suggested by the Examiner, would render the device of Dunn less suited for its intended purpose, because the vacuum bandage of Coffey would tend to suck the drugs supplied by the Dunn device out of the patient. The drugs would be removed from the patient resulting in a decreased chance to treat the tissues adjacent the implanted Dunn device. Since the drugs are intended to be released into the tissue to be treated it would be illogical to attempt to vacuum the drugs entirely out of the patient. That is, the entire purpose of implanting the drug-delivering Dunn surgical device would be impeded, or at least rendered less effective, if Dunn were combined with Coffey. A person skilled in the art would realize that applying a vacuum about the device of Dunn would draw off the drugs as they are released from the Dunn device, defeating its purpose. Therefore, one skilled in the art would never consider it obvious to combine the device of Coffey with that of Dunn.

Thus, for all the above reasons Applicants respectfully submit that the proposed prior art combination of Coffey with Dunn is not obvious. There is no suggestion or motivation provided, either by the references relied on by the Examiner or by knowledge generally available to one of ordinary skill in the art, to modify such references or to combine the disclosures thereof in the manner proposed by the Examiner. The combined disclosures relied upon by the Examiner fail to give rise to a reasonable expectation that applying a reduced pressure to hard tissue, such as bone, as claimed by Applicants should even be attempted or succeed. Further, the proposed combination would render Dunn less suited for its intended purpose or inoperable.

Accordingly, Applicants respectfully request that the Examiner withdraw the rejections of claims 1-13.

In view of the foregoing amendments and remarks, it is believed that the claims in this application are now in condition for allowance. Early and favorable reconsideration is respectfully requested. The Examiner is invited to telephone the undersigned in the event that a telephone interview will advance prosecution of this application.

**Application No. 10/647,068**  
**Docket No. 0101-P02977US1**

**Art Unit: 3732**  
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Respectfully submitted,



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